

**REMARKS**

**1. Amendments to the Specification**

Applicants have amended the Specification to omit embedded hyperlinks. No new matter has been added.

**2. Amendments to the Claims**

Claims 1-26 are pending. Claims 8-18 and 21-24 are withdrawn from further consideration by the Examiner. Claims 3, 5, 8-11, 13, 15-18, and 21-24 are herein cancelled. Claims 1-7, 19, 20, 25 and 26 are under examination.

Claim 1 has been amended. Support for claim 1 is found in the Specification at page 17, lines 6-9; page 12, line 8; and page 23, lines 17-19.

Claim 2 has been amended. Support is found in the Specification at page 17, lines 6-9; page 12, line 8; and page 23, lines 17-19.

Claim 4 has been amended to depend from claim 2.

Claim 12 has been amended. Support for claim 12 is found in the Specification at page 19, lines 5-10, and page 12, line 8.

Claim 19 has been amended to depend from claim 2.

Claims 25 and 26 have been amended to depend from claim 19.

New claim 27 is herein added. Support for claim 27 is found in the Specification at page 19, lines 5-10, page 17, lines 6-9, page 16, lines 15-25.

No new matter has been added.

### **3. Objections to the Claims**

The Examiner objects to claims 25 and 26 as reading upon more than one elected invention. Applicants have amended the claims to depend directly from claim 19, thus reciting a single invention. Applicants request that the rejection be withdrawn.

### **4. Claim Rejections under 35 U.S.C. § 112, Indefiniteness**

The Examiner rejects claims 1-7, 19, 20, 25, and 26 as being indefinite for the recitation as “substantially the same amino acid sequence as shown in SEQ ID NO: 2.” Applicants have amended the claims to omit this language. Applicants request that the rejection be withdrawn.

The Examiner rejects claim 2 as indefinite “because the claimed peptide may be interpreted as a fragment of SEQ ID NO: 2 or a full-length SEQ ID NO: 2, which is a partial peptide of another protein.” Applicants have amended the claim to clarify that the peptide of interest is 8-14 amino acids long, thereby clarifying the length of the peptide. Applicants request that the rejection be withdrawn.

### **5. Claim Rejections under 35 U.S.C. § 102**

The Examiner rejects claims 1-4, 6, 7, 19, 20, 25, and 26 as anticipated by Boeckle et al. (Virol. 293: 103-107 (2002), of record) or, alternately, Tang et al. (WO 01/55437). The Examiner states that both references disclose SEQ ID NO: 2, and both references disclose SEQ ID NO: 6. The Examiner states that the disclosure of the sequences anticipates the present invention because “the properties recited in claims 2 and 3 describe an intrinsic property of SEQ ID NO: 2.”

Applicants note that claim 2 has been limited to a peptide that is 8-14 amino acids long. Although Boeckle and Tang discloses the protein sequence SEQ ID NO: 2, they are silent about

the specific length of a partial peptide, neither does either reference disclose an epitope that is recognized by CTLs when bound to HLA-A24 or HLA-B55. Thus, neither Boeckle or Tang recites every limitation of the claims. Thus, a rejection based on anticipation is not applicable. Applicants request that the rejection be withdrawn.

#### **6. Claim Rejections under 35 U.S.C. § 103**

The Examiner rejects claims 2-4, 6, 7, 19, 20, 25, and 26 as being unpatentable over Konya et al. (J. Gen. Virol. 78:2615-20 (1997)), in view of Boeckle et al.. The Examiner states that because Konya teaches “identifying CTL epitopes of the HPV-16 E2 protein for developing cancer vaccine, wherein many small peptides were found to contain HLA binding motif and have CTL-inducing activity” and Boeckle discloses the HPV-8 protein, one of skill would find it obvious to apply the method of Konya for developing a HPV-8 vaccine using the sequence of Boeckle.

The Examiner also rejects claims 2-4, 6, 7, 19, 20, 25, and 26 as unpatentable over May et al. (J. Gen. Virol. 72:2989-97 (1991)).

The Examiner rejects claim 5 as unpatentable over Konya et al., in view of Boeckle et al., further in view of Kubo et al. (J. Immunol. 152:3913-24 (1994)). Applicants note that claim 5 has been cancelled.

Amended Claim 2 is directed to a partial peptide which can induce CTLs in a HLA-A24 or HLA-B55 restricted manner.

#### *Teachings in the Cited Art*

Boeckle discloses that PBF was identified as a human cellular factor that recognizes and binds to E2 binding sites of human papillomavirus type 8 gene. Although papillomavirus plays an important role in the onset of some kinds of cancer, Boeckle is silent about the possibility of PBF or its epitope peptides as a cancer vaccine. The art would not imagine human origin PBF,

or more particularly any peptides derived from the protein, could be effective as a cancer antigen vaccine.

Tang discloses polynucleotides and peptides obtained from a various cDNA libraries. Although it discloses the amino acid sequence of SEQ ID NO:2 of the instant application, Tang is silent about any function of the protein.

Konya discloses identification of a CTL epitope in the papillomavirus type HPV-16E2 protein for the development of a cancer vaccine. Konya studied epitopes in a protein derived from a virus but not those derived from a human. Konya is silent about PBF.

May discloses patterns of cellular proteins that bind to non-coding regions of epidermodysplasia verruciformis associated human papillomaviruses 8 (HPV-8) genome. May is silent about using cellular proteins that bind to HPV-8 as a cancer vaccine. May is silent about PBF.

Kubo discloses peptide motifs for HLA-A1, A3, A1 I and A24 antigens. Kubo is silent about PBF.

*Combination of Boeckle and Konya and Boeckle and May*

The Examiner alleges that the partial peptides of the instant application are obvious over Boeckle in view of Konya. However, Konya discloses the use of proteins derived from a virus (HPV-E1 and -E2) and gives no information about the use of protein or peptides derived from a human for a vaccine. There is no indication that one of skill would spontaneously come up with the idea of using a protein of human origin, PBF, disclosed in Boeckle, based on Konya's disclosure of proteins derived from a virus.

Likewise, May does not disclose any information about PBF or peptide vaccines. Accordingly, one of skill in the art would not find the combination using PBF or its partial

peptides as a CTL inducer or cancer antigen vaccine. Thus, Applicants request that the rejection be withdrawn.

### CONCLUSION

Applicants submit that the claims as amended well-define subject matter free of the prior art. The favorable actions of allowance of withdrawal of the standing rejections and allowance of the claims are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell Reg. No. 36,623 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By   
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